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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,289	03/01/2004	Kati A. Chevaux	1010/0102US4	9500
32260	7590	09/24/2009		
NADA JAIN, P.C. 560 White Plains Road, Suite 460 Tarrytown, NY 10591			EXAMINER WINSTON, RANDALL O	
			ART UNIT	PAPER NUMBER
			1655	
			NOTIFICATION DATE	DELIVERY MODE
			09/24/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

paralegal@nadajain.com  
nada@nadajain.com

# Office Action Summary

## Application No.

10/790,289

## Applicant(s)

CHEVAUX ET AL.

## Examiner

Randall Winston

## Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 75-115 is/are pending in the application.
- 4a) Of the above claim(s) 75-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 80-115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 12/16/2008 has been entered.

Claims 80-115 have been examined on the merits (Examiner acknowledges that claims 1-74 have been cancelled and claims 75-79 remains withdrawn from consideration.)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 80-115 are rejected under 35 US 103(a) as being unpatentable over Romanczyk, Jr (US 5,554,645) in view of Wideman et al. (6,127,421).

A food product (i.e. non-chocolate) comprising (i) cocoa polyphenol (i.e. a polyphenol compound of formula An of claim 32) and (ii) L-arginine in various amounts is claimed.

Romanczyk teaches (see, e.g. figure 3, column 7 lines 20-27 and entire patent) a food composition comprising a cocoa polyphenol (i.e. a polyphenol compound of formula An of claim 32 is within figure 3 of Romanczyk, named (-) epicatechin) is used for anti-tumor purposes). Romanczyk, however, does not expressly teach that the active ingredient of L-arginine is contained within the claimed food composition nor does Romanczyk teach all the claimed forms of the food composition and all the claimed amounts/ranges used for anti-tumor purposes.

Wideman beneficially teaches (see, e.g. column 2 lines 30-39) that the incorporation of L-arginine within a food product is used for anti-tumor purposes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Romanczyk's food composition to include the other claimed active ingredient of L-arginine as taught by Wideman within Romanczyk's food composition because the two above combined teachings as a whole would create the claimed food composition used for anti-tumor purposes. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. the active ingredients of cocoa polyphenol and L-arginine used for an anti-tumor purpose), in order to form a third composition to be used for the same purpose." Furthermore, the adjustment of other conventional working conditions (e.g. determining suitable

amounts/ranges of each active ingredient (i.e. cocoa polyphenol and L-arginine) within the claimed composition to intrinsically have some and/or any effective functional effect when administered to a subject and the modification of one form for another of the food composition such as non-chocolate pet food and/or as a peanut), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note, the intended use of the above claimed composition (i.e. to induce a physiological increase in nitric oxide) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Applicant's arguments have been carefully considered but they are not deemed persuasive. Applicant argues that combining the procyanidin (cocoa polyphenol) taught within Romanczyk and the arginine taught within Wideman fails to teach that the compounds cited in Applicant's claims have nitric oxide effects. Moreover, Applicant

argues that the procyanidin (cocoa polyphenol) of Romanczyk and the arginine of Wideman cannot be optimized and/or amount to routine optimization to have a nitric oxide effect when such effects are not suggested by the cited prior art.

Although Applicant argues that combining the procyanidin (cocoa polyphenol) taught within Romanczyk and the arginine taught within Wideman fails to teach that the compounds cited in Applicant's claims have nitric oxide effects, Applicant argument is not found persuasive because the intended use of the instantly claimed composition (i.e. to induce a physiological increase in nitric oxide) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the composition reasonably suggested by the combined teachings of the cited references (see, e.g., MPEP 2112). In addition, based upon the beneficial teachings provided by Romanczyk and Wideman, as a whole, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instantly claimed ingredients for anti-tumor purposes. Please note, as discussed in MPEP Section 2114.06, "it is well known to be *prima facie* obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. the active ingredients of cocoa polyphenol and L-arginine used for an anti-tumor purpose), in order to form a third composition to be used for the same purpose."

Moreover, although Applicant argues the procyanidin (cocoa polyphenol) of Romanczyk and the arginine of Wideman cannot be optimized and/or amount to routine optimization to have a nitric oxide effect when such effects are not suggested by the cited prior art, Applicant argument is not found persuasive because the instant

specification provides for very broad amount ranges of the instantly claimed ingredients therein - including from about 1  $\mu$ g to about 10 g per unit dose of cocoa polyphenol and of l-arginine therein so as to provide the effect of stimulating nitric oxide production, as well as arresting cancer cells and/or modulating apoptosis (among other effects), in a subject in need thereof (see, e.g., page, 9 lines 4-12, and page 20, lines 13-32, of the instant specification). Accordingly, the amounts of cocoa polyphenol and arginine disclosed by the respective reference teachings (i.e., Romanczyk discloses high levels/percentages of cocoa polyphenol within such non-chocolate food compositions for inhibiting tumor growth; and Wideman discloses the prior art use of an anti-tumor feed composition comprising 0.92% or 2.40% of arginine therein) would intrinsically provide the instantly claimed *in vivo* functional effect with respect to increasing nitric oxide, upon ingestion thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655